Organization

Office of the Commissioner

Office of Foods

Office of Regulatory Affairs

Center for Food Safety & Applied Nutrition

Center for Veterinary Medicine

Center for Devices & Radiological Health

Center for Drug Evaluation & Research

Center for Biologics Evaluation & Research

Center for Tobacco Products

National Center for Toxicological Research

A Presence Around the Globe

- Headquarters - Maryland
- International -India, China, Latin America, Europe, Middle East
- Regional Offices– 5
- District Offices - 20
- Resident Posts/Border Stations -177
- Field Laboratories - 13
- Mobile Labs - 2
- Total ORA Investigators: ~1800
- Total ORA Analysts: ~ 900

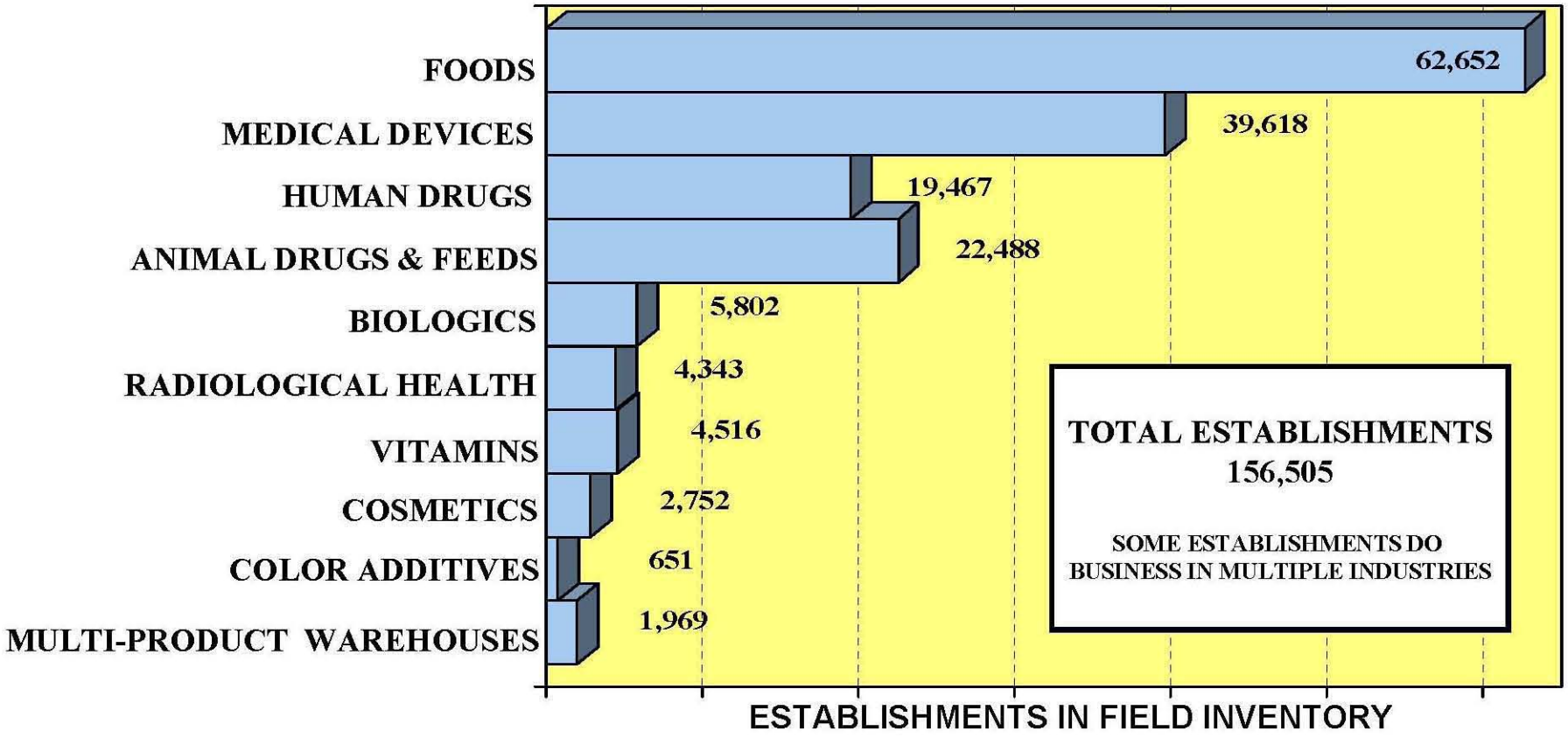
FDA Regulated Products

- Products regulated by FDA include:
  - All foods except non-game meat and poultry
    - Human food, Animal feed and Pet food
  - Cosmetics
  - Dietary Supplements
  - All legal drugs (prescription and non-prescription, animal and human)
  - Biological products including blood products, vaccines, and tissues for transplantation
  - Medical devices and products that emit radiation
  - Tobacco products

- Combined, these products represent about 1 Trillion dollars/year or 25% of consumer spending
- FDA's budget is approximately $1.6 billion a year -about $4/year per taxpayer

DOMESTIC INDUSTRY

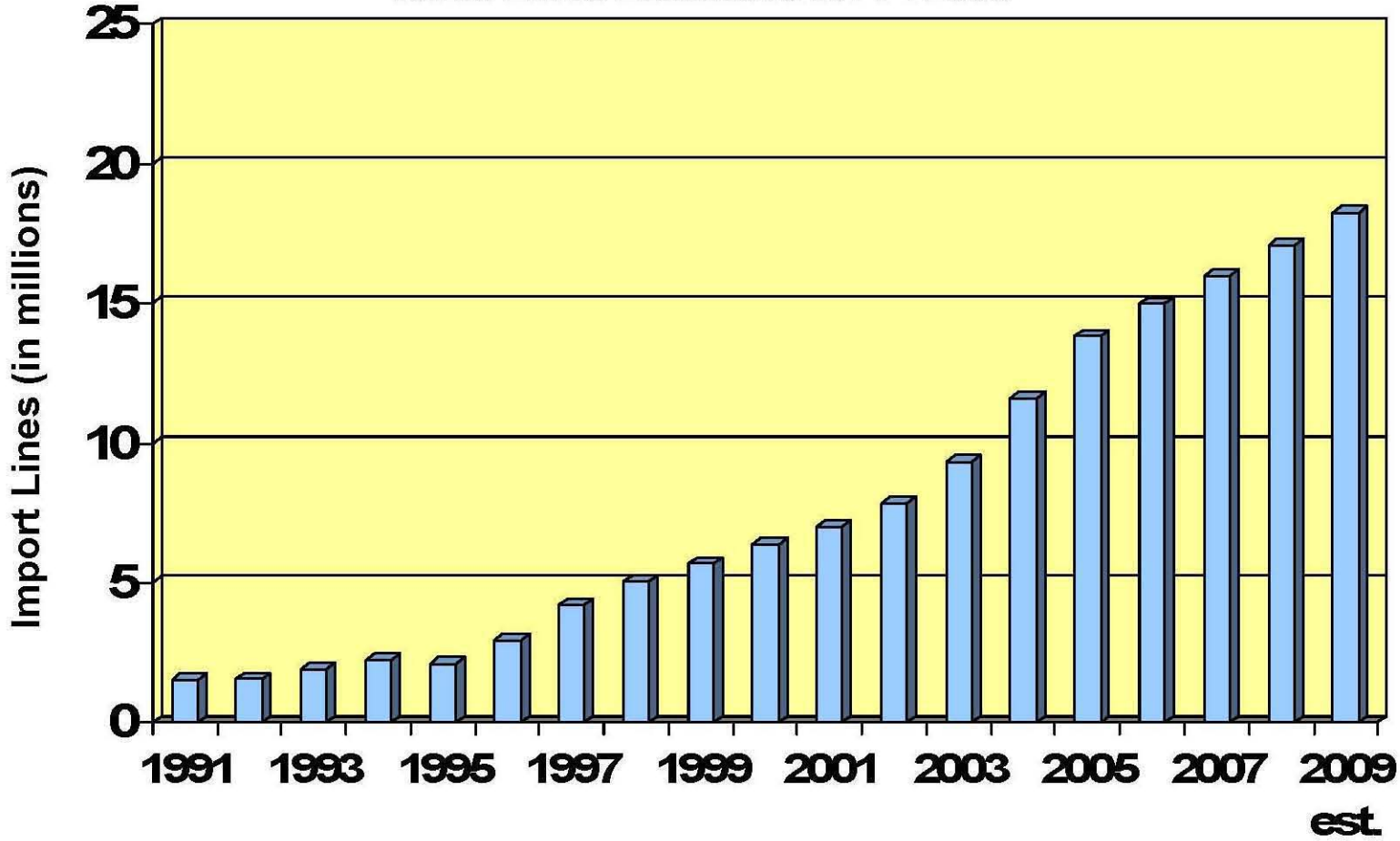
HOW BIG IS OUR JOB ?



- Note: this graphic does not include tobacco products

Import Volume History

15.9M Lines Actual for FY2007
17M Lines Estimated for FY2008
18.2M Lines Estimated for FY2009



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Consumer Safety Officers

- Consumer Safety Officers (CSOs) follow a standard training curriculum, which ensures that each will possess the knowledge, skills, and abilities necessary to successfully support FDA's mission.
- CSOs achieve certifications at Levels I, II and III
- Level I
  - Formal training (12 classroom courses, 39 online courses)
  - On the Job Field Training & Experience
  - Performance audit

- Level II
  - Training and experience required in a specific program/commodity area
    - Seafood Products
    - Medical Devices
    - Blood Bank & Plasma Center
    - Drug Investigator
    - Cooperative Programs: Retail Food, Milk, Shellfish, Interstate Travel
- Level III
  - Drug Investigator/Pharmaceutical Inspectorate

Qualities of a Good CSO

Excellent Interpersonal Skills

Knowledgeable, Dependable, Organized. Seeks to be Challenged.

Cultivates professional relationships

Perceptive and intuitive. Sees the Big Picture.

Maintains scientific and technical competency

Educator and teacher

FDA Inspection Authority

Food, Drug and Cosmetic Act 21 USC §374

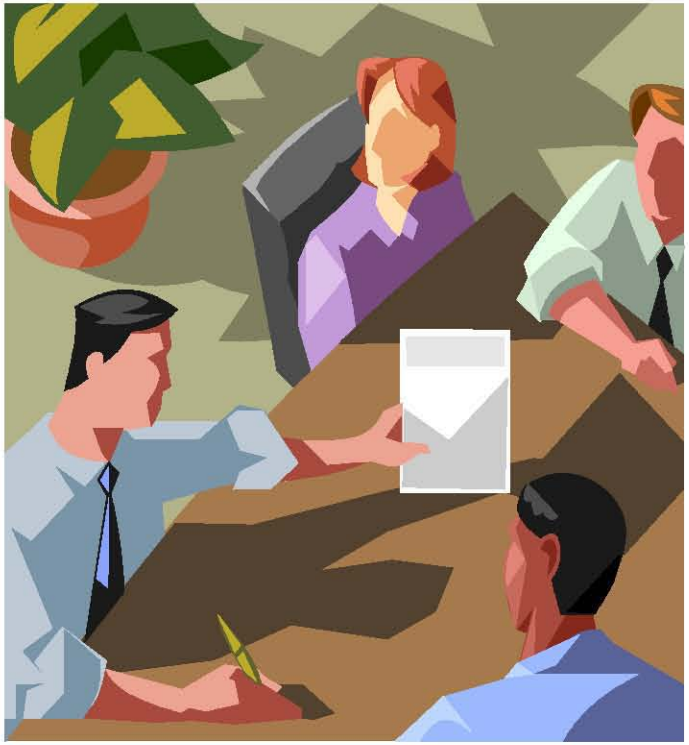
"704(a)(1): For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein…"

FDA Inspections

- Preparing for the Inspection
  - Announced vs. Unannounced
  - Review previous inspection and compliance history
  - Review of Guidance Documents, CPs, Guides to Inspection
- Review assignment
- Prepare an inspection tool kit

FDA Inspections

- Initiating the Inspection
  - Meet with most responsible person at firm
  - Present credentials
  - Issue FDA 482 Notice of Inspection
  - Initial discussion with management



FDA Inspections

- Review of Operations
- Procedures
- Observe and Evaluate
  - Observe process flow and employees at work
  - Look for critical control points in the manufacturing process whereby adulteration could occur
  - Evaluate sites for sampling

FDA Inspections

- Develop and Document Evidence
  - Physical Inspection
  - Sampling (Environmental, in-line, finished product)
  - Photography
  - Discussions with employees
  - Record Collection

FDA Inspections

- Close-Out Discussion
  - Discuss Observations with Management
  - FDA 483: Inspectional Observations
  - FDA 484: Receipt for samples
  - Solicit Firm's responses to observations
    - Corrections made
    - Plans for future actions

FDA Inspections

- Final Report
  - Establishment Inspection Report (EIR)
  - Sample results
  - Evidence
  - Classification of Inspection

FDA Inspections

- Enforcement Actions
  - Voluntary Compliance by Firm
    - Follow-up inspections
  - Enforcement Actions
    - Warning Letter
    - Regulatory Meetings
    - Seizures
    - Injunctions
    - Penalties

On the Front Line - Protecting and Advancing Public Health

- **FDA protects the public health** by assuring safety, efficacy, and security of human/animal drugs, biological products, medical devices, food and cosmetics, and products that emit radiation.
- **FDA advances the public health** by helping speed innovations to make medicines and foods more effective, safer, and affordable; and helping the public obtain accurate, science-based information
- **FDA accomplishes its mission** by establishing and enforcing high product standards and other regulatory requirements authorized or mandated by the Federal Food, Drug and Cosmetic Act (FD&C Act), its amendments, and other public health laws